



## Health Research Authority

### North West - Lancaster Research Ethics Committee

Barlow House  
3rd Floor  
4 Minshull Street  
Manchester  
M1 3DZ

**Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.**

11 July 2018

Professor Claire Foster  
Professor of Psychosocial Oncology & Director of Macmillan Survivorship Research Group  
University of Southampton  
Faculty of Health Sciences, Building 67  
Highfield Campus, University of Southampton  
University Road, Southampton  
SO17 1BJ

Dear Professor Foster

<b>Study title:</b>	<b>HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer</b>
<b>REC reference:</b>	<b>16/NW/0425</b>
<b>Protocol number:</b>	<b>RHM CAN1199</b>
<b>Amendment number:</b>	<b>Substantial Amendment 8</b>
<b>Amendment date:</b>	<b>08 June 2018</b>
<b>IRAS project ID:</b>	<b>202342</b>

This amendment submits for review: the 24 month breast, NHL, endometrial, ovarian, cervical and vulval time point Questionnaires, along with a contents page of measures selected. This change does not affect the recruiting sites as follow up questionnaires would be sent by the coordinating centre.

The above amendment was reviewed 28 June 2018 by the Sub-Committee in correspondence.

### **Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

### **The Sub Committee raised no ethical issues with this amendment**

### **Approved documents**

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		14 June 2018
Non-validated questionnaire [HORIZONS 202342 24 month Questionnaire Ovarian ]	1.0	01 June 2018
Non-validated questionnaire [HORIZONS 202342 24 month Questionnaire Vulval ]	1.0	01 June 2018
Non-validated questionnaire [HORIZONS 202342 24 month Questionnaire Breast ]	1.0	01 June 2018
Non-validated questionnaire [HORIZONS 202342 24 month Questionnaire Cervical ]	1.0	01 June 2018
Non-validated questionnaire [HORIZONS 202342 24 month Questionnaire Endometrial ]	1.0	01 June 2018
Non-validated questionnaire [HORIZONS 202342 24 month Questionnaire NHL ]	1.0	01 June 2018
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 8	08 June 2018
Other [Contents of HORIZONS 24 Month Questionnaires]		

### **Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

### **Working with NHS Care Organisations**

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

### **Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

**16/NW/0425:**

**Please quote this number on all correspondence**

Yours sincerely



pp

**Professor Carol Haigh  
Chair**

E-mail: [nrescommittee.northwest-lancaster@nhs.net](mailto:nrescommittee.northwest-lancaster@nhs.net)

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Mrs Sharon Davies-Dear, University Hospital Southampton NHS  
Foundation Trust  
Mr Richard Brooks*

**North West - Lancaster Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 28 June 2018**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Carol Haigh		Yes	Chair
Mrs Karen Wright	Principal Lecturer Mental Health & MPhil/PhD student	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Nina Bakhshayesh	REC Assistant